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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/316,001	05/21/1999	ROGER V. KENDALL	FSC-6	7220

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EXAMINER

NOLAN, PATRICK J

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 03/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/316,001

Applicant(s)  
Kendall et al.

Examiner  
Patrick J. Nolan

Art Unit  
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 7/26/01 and 1/14/01.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 12-18 and 20-41 is/are pending in the application.
- 4a) Of the above, claim(s) 22-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-18, 20, 21, and 38-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

#### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, filed on 1/14/02, has been entered.

2. A restriction was required under 35 U.S.C. § 121 in the parent application, as set forth in Paper No. 4, mailed 11/17/99. Applicant elected Group II, Claims 12-18, drawn to a protein composition, with traverse. This restriction requirement is hereby reiterated.

The requirement is still deemed proper for the reasons of record as set forth in Paper No. 8, mailed 7/29/00, and is therefore made FINAL.

3. Accordingly, Claims 22-29 and 30-37 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to nonelected inventions.

Claims 12-18, 20-21, and 38-41 are being acted upon.

Applicant is advised that a request for the rejoinder of Claims 22-37 in view of *In re Ochiai* 37 USPQ2d 1127 (Fed. Cir. 1995) will be considered upon allowance of the product claims. Applicant is further advised, however, that only method claims of the exact same scope would be rejoined. Additionally, Applicant is advised that new 35 U.S.C. 112, first paragraph considerations may be required upon rejoinder of the method claims.

4. New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings

are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

Corrections other than Informalities Noted by Draftsperson on form PTO-948. All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections. Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application.

5. In view of Applicant's Amendments and Remarks, filed 1/14/02, only the following rejections remain.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 12-18, and newly added Claims 20-21 and 38-41, stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,026,728, (1991, of record) in view of Caughey et al. (1983, of record) or Gibson et al, (1980, of record) or U.S. Patent No. 4,455,298 (1984, of record), for the reasons set forth

in Paper No. 10, mailed 9/26/00.

Applicant arguments, filed 1/14/02, have been fully considered but are not found persuasive. Applicant argues that "Even if the basis for rejection is assumed to be correct (although applicants do not admit this), data of record establish significant advantages of the combination of applicants' invention which would not have been expected from the prior art." However, said "advantages," e.g., Th2 to Th1 shift, comprise unclaimed limitations. It remains the Examiner's position that the combination of two known anti-inflammatory compositions to create an improved anti-inflammatory composition would be obvious. Regarding the teachings of Belkowski, said teachings apply only to the highly artificial collagen-induced arthritis model for which a single set of non-scientifically significant results (Table 3.1, differences between Perna and DMG-Perna) are taught. Said results can not then be said to teach away from the composition of the instant claims as said results are inconclusive.

8. The following are new grounds for rejection necessitated by Applicant's amendment.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 12-14 and 20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Belkowski, S.M., (1991, of record).

Belkowski teaches a composition comprising a dimethylglycine component and a *Perna canaliculus* component, suitable for oral administration or as a dietary supplement, further comprising freeze-dried ground whole *Perna canaliculus* mussel (see particularly pages 58-61). Note that the reference does not disclose a composition which contains "non-injectable" forms of both PCE and DMG. However, the term "non-injectable" has not been defined in the specification. It is the Examiner's position then that any form of the claimed composition that would be

suitable for injection would also be suitable for use in non-injected routes of administration because injectable forms of compositions are necessarily sterile and generally more pure than are non-injectable compositions. Thus, the injectable form of DMG taught by Belkowski anticipates the non-injectable form of the composition of the instant claims. Additionally, the specification discloses at page 5, "The DMG and PCE components may be administered via the same route or they may be administered via different routes. For example, the DMG and PCE may both be administered orally, either simultaneously or at different times." Thus, the composition of the reference anticipates the composition of the instant claims.

11. Claims 12-18, 20-21, and 38-41 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, composition comprising dimethylglycine and *Perna canaliculus* both in a non-injectable form for administration (Claim 12), or a dimethylglycine formulation in a non-injectable form and a *Perna canaliculus* in a non-injectable form (Claim 15).

Applicant's amendment, filed 1/14/02, asserts that no new matter has been added. Applicant has indicated that the disclosure at page 5 of the specification supports the new limitation. However, support has only been found for oral or suppository forms of the claimed composition. Non-injectable forms would encompass a broader genus of formulations, including for example, forms for nasal administration.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Patrick J. Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:30 pm. A message may be left on the examiner's

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voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.



Patrick J. Nolan, Ph.D.  
Primary Examiner  
Technology Center 1600  
March 13, 2002